This paper provides a short overview of certain international considerations in Biopharma Patent Litigation.

Issues arising in domestic US litigation have been addressed in the Commentary on Patent Litigation Best Practices: Unique Aspects of Biopharma Patent Litigation Chapter which provides Best Practice recommendations to counsel, parties, and the courts on how to navigate the relevant statutes and unique landscape involved in biopharma litigation.

When it comes to international practice, although systems may differ significantly between the US and Europe, similar issues in Biopharma patent litigation do arise.

Entry on the market of generics and biosimilar: regulatory, patent and competition law

Biopharma patent litigation is an area where there is still less uniformization than in other technical area (like in Telecoms for instance). The main reason being that this sector contains a regulatory layer that frameworks or has an impact on litigation, in particular in terms of timing.

As it stems from the Commentary, “The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) created an Abbreviated New Drug Application (ANDA) procedure regulated by the Food and Drug Administration (FDA), that in certain circumstances allows generic drugs to be approved based upon the same safety and efficacy test data earlier produced and used by the drug’s originator to gain the first FDA approval of that drug. Among the circumstances addressed are those relating to whether the proposed marketing of the generic drug would occur after the patents pertaining to the original “brand name” drug expire, or if not, whether the ANDA applicant can certify that the proposed generic product would not infringe any valid claim of the originator’s patents pertaining to the proposed generic product”.

This Act also “establishes a framework for addressing patent disputes when a generic manufacturer seeks to obtain FDA approval of the proposed generic product. The Act first requires the originator of each FDA-approved drug to list its patents pertaining to that drug in an FDA-maintained registry, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.” This framework then requires each generic manufacturer filing an ANDA with the FDA—commonly referred to as a “patent certification”—to include one of the following certifications with its application: (1) that the drug has not been patented; (2) that the patent has already expired; (3) that the generic drug will not go on the market until after the expiration of the relevant Orange-Book-listed patents; or (4) that each relevant Orange-Book-listed patent is not infringed or is invalid.

In the US, listing of drugs on the Orange book is therefore an effective tool to limit launch at risk of generics or biosimilars.

But, recently, in Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals, the FTC filed an amicus brief in relation to a potential abuse of the Orange book listing process arguing that Jazz’s listed a patent claiming a distribution system which seems not to meet the Orange book

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2 This publication lists all commercial drug products approved in the United States along with the patents relevant to the active drug ingredient, as well as formulations, inert ingredients, and uses. Typically listed patents include compound patents, formulation patents, and method of treatment or use patents.
requirements. The Orange book requires that only drugs that claim a drug or method of using the drug be listed. The Panel will discuss this recent issue.

In Europe, application for marketing authorization of medicinal products is subject to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. It provides with 8 years of data exclusivity during which the marketing-authorisation holder benefits from the exclusive rights to the data. This means that a generic or biosimilar applicant cannot cross-refer to this data in support of its own marketing authorization. After that period it is possible to use the abbreviated application for a marketing authorization (based on the innovator's data). But it is followed by 2 years of market protection during which a generic or biosimilar cannot be placed on the market. 1 additional year of market protection can be obtained in a case of a new therapeutic indication which brings significant clinical benefit in comparison with existing therapies. Generics or biosimilars can therefore not come on the market before 10 to 11 years from the grant of the marketing authorization to the innovative product. After that period, and although patent rights may still be in force, generics and biosimilars can come on the market. With no more regulatory protection, the patentees are therefore relying on their patents and the possibility to obtain injunctions in order to have their IP rights respected.

But the EU competition authority is closely monitoring the activities of pharmaceutical companies and recently launched investigations against Teva for potential misuse of the patent system accusing Teva of trying to extend its patent monopoly through the filing of divisionals. The panel will address this issue.

Injunctions / exclusion orders

In Europe, the use of preliminary or permanent injunctions to prevent or stop infringement is widely used and the biopharma sector does not make an exception. Due to the regulatory landscape and data and market protection awarded to innovators, injunctions are usually granted during the last years of the patent protection. But recent decisions in Europe have granted preliminary injunctions on the basis of patent applications. The panel will discuss whether granting injunctions on the basis of claims that are not finally granted is acceptable or not.

In the US, exclusion orders can be granted by the International Trade Commission to ban imports of infringing products; but are they used in biopharma patent litigation? The panel will address this question.

Compulsory licensing

Over the last couple of years was COVID-19 and its consequences over research, patenting and making drugs available widely. Legislations relating to compulsory licences have been revived and patent litigation involving key players of the vaccine field have now started, with the aim to only get monetary compensation rather than injunction. The Doha Declaration, article 31bis of the TRIPS agreement and Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022 which covers production and supply of COVID-19 vaccines allows countries to impose compulsory licences.
The panel will discuss the consideration of compulsory licensing in their respective jurisdictions.

**Influence of foreign judgements**

Although court systems are different from one country to another, courts are usually deciding over the same or similar patents covering biopharma innovative products. In Europe, where patent court systems are fragmented because in the hands of each national court system due to the absence of any unitary patent (i.e. unique title covering some of European union countries), judgements handed down in one country may have influence on pending proceedings and decisions to come in other countries.

The upcoming European patent with unitary effect and the Unified patent court (UPC - competent for ordinary European patents, i.e. bundle of national patents and European patents with unitary effect) will cover 17 European Union countries (and more to come in the future). The United Kingdom which is no more part of the European Union is a country where patent litigation will be run in parallel to foreign proceedings, in particular the UPC.

The panel will discuss the influence of the foreign decisions in their respective countries with a particular focus on the impact of the future UPC.

**Litigating second medical use / dosage patents**

The patent law system allows innovators to obtain patents not only on the drug itself or manufacturing method thereof, but also on second medical use or dosage schemes. Targeting specific patient population is also a trend in biopharma patents. But when it comes to litigate these patents, validity challenges may be more difficult to overcome than mere product patents. The same goes as to evidencing infringement of second medical use patents.

The panel will discuss these issues according to their respective jurisdiction.